Remarks

Claims 21, 24-26, 29, 32-34 and 37-52 are pending. Claims 1-20, 22, 23, 27, 28, 30, 31, 35, and 36 are cancelled.

The final Office Action mailed August 6, 2009 rejects pending claims 21, 25, 29, 33, 37, 39, 41, 44, 46, 47, 50 and 52 under 35 USC §103(a) as being unpatentable over Patel et al. (WO 01/37808) and Lilley et al. (WO 01/35925) in view of Alford (US 3,937,825) or Jans et al. (US 5,824,336). Claims 24, 26, 32, 34, 38, 40, 42, 43, 45, 48, 49 and 51 stand objected to but are indicated as "of allowable subject matter" (see page 4, Final Office Action dated August 6, 2009).

With the present Amendment and Reply, Applicants place this application in condition for allowance by following the Examiner's Action and hereby present the following claim amendments:

- · independent claims (i.e., claims 21, 29, 41, and 47) are cancelled;
- claim 24 is amended to independent form by incorporating the subject matter of claim 21:
- claim 25 is amended to depend from claim 24:
- · claim 26 is amended to depend from claim 24:
- claim 32 is amended to independent form by incorporating the subject matter of claim 29:
- claim 33 is amended to depend from claim 32:
- claim 34 is amended to depend from claim 32;
- claim 37 is amended to depend from claim 24:
- claim 39 is amended to depend from claim 32:
- claim 42 is amended to independent form by incorporating the subject matter of claim 41:
- · claim 44 is amended to depend from claim 42;
- · claim 45 is amended to depend from claim 42;
- claim 46 is amended to depend from claim 42:
- claim 48 is amended to independent form by incorporating the subject matter of claim 47:
- claim 50 is amended to depend from claim 48:
- claim 51 is amended to depend from claim 48; and
- claim 52 is amended to depend from claim 48.

In view of the Examiner's note regarding the difference between lactose and sugar, Applicants note that claims 24, 32, 42, and 48 currently recite that the carrier material is selected from the group consisting of starch, saccharose, and lactose.

The amendments presented herein are believed to place the claims in condition for allowance. No new matter is presented. Applicants reserve the right to pursue one or more continuation applications directed to the subject matter cancelled during prosecution. Favorable consideration of the pending claims is earnestly solicited in the form of a notice of allowance.

Rejection Under 35 USC §103(a)

As noted above, claims 21, 25, 29, 33, 37, 39, 41, 44, 46, 47, 50 and 52 stand rejected under 35 USC §103(a) as being unpatentable over Patel et al. (WO 01/37808) and Lilley et al. (WO 01/35925) in view of Alford (US 3,937,825) or Jans et al. (US 5,824,336). The Examiner contends that Patel et al. provide the coated instant particles, inclusive of benzepril over sugar or lactose or starch of 30-35 mesh size. The Examiner also contends that Lilley et al. provide actives for animal oral delivery in feed as very small particles. The Examiner relies on Alford and Jans et al to allegedly show how the coated particles can be mixed with animal feed substrate and pelleted. Thus, the Examiner concludes that it would have allegedly been obvious to a person of ordinary skill in the art at the time of the invention desiring to utilize a protected feed additive to use one of Patel et al. or Jans et al.'s additives in order to provide animal acceptance and include desired nutrients and drugs. Examples of feed components with actives are allegedly shown by Alford and Jans et al.

The present composition and method are not obvious for the reasons set forth in the Amendment and Reply filed May 19, 2009, namely:

- 1. There is absolutely no reasonable expectation of success from the cited references. Mixtures of the recited particles with an animal feed substrate, such as yeast, are not proposed or disclosed anywhere. Thus, the particle size, as claimed in the present invention, is of no concern at all in the Patel et al reference. Without recognition of the problem to be solved, there can be no expectation of success in a solution.
- Patel et al., by no means, provide a motivation to select a benazepril formulation. Further, there is no appreciation in the Patel et al reference of the pronounced bitter taste of benazepril and its use in veterinary applications. Moreover, without such appreciation there can be no

- suggestion for the need to make benazepril appealing to animals for feed consumption.
- 3. Patel et al.'s composition actually teaches away from the present invention. Patel et al. require particles to be coated with a combination of active ingredient and a hydrophilic surfactant. The particles of the present invention are coated with the active ingredient, alone, and are then further protected by a second, discrete layer.
- 4. Embodiments of the presently claimed invention represent successful commercial animal health products around the world. The commercial product provides needed medicines to cats (renal insufficiency) and dogs (congestive heart failure) in a form (feed) acceptable to the animals. The Patel et al. reference is in a different technical field and provides no motivation to mask bitter tasting drugs that would be subjected to breakage and exposure within the mouth.
- The cited secondary references are insufficient to cure the deficiencies of the primary reference.

Accordingly, the presently claimed invention is not rendered obvious even by a combination of the cited references. None of the cited references discloses the specific structure of the inventive composition, including the size range and recognition of the particular bitter component.

While Applicants do not acquiesce in the propriety of the rejection for at least the reasons set forth above, Applicants cancel independent claims 21, 29, 41, and 47. The subject matter of the cancelled independent claims is incorporated into the dependent claims as outlined above. This Amendment and Reply, as outlined by the last Office Action, overcomes the objection and claims acknowledged allowable subject matter.

U.S. Patent Application Serial No. 10/506,937 WCSR Docket Number N079 1030.US Novartis Reference H-32407A

The present claims are in condition for allowance and respectfully request such action. If the Examiner has any remaining issues for resolution, he is encouraged to telephone the undersigned for expeditious handling.

Respectfully submitted,

Date: 11/2/09 amy N In

Amy H. Fix Reg. No. 42,616

Womble Carlyle Sandridge & Rice, PLLC

Post Office Box 7037 Atlanta, Georgia 30357-0037

Telephone: (919) 484-214 Facsimile: (919) 484-2071